APR 2 9 2002

K012556

Pg 1 of 7

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person:
Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis MN, 55369
Ph: 888-856-4870
Fax: 763-488-3350

Date Prepared: August 6, 2001

Trade Name: Reprocessed Guidewire

Classification Name: and Number:
Guidewire
Class II, 21CFR §876.5010 & 21CFR §876.1500

Product Code: FGE & KOG

Predicate Device(s): The reprocessed guidewire is substantially equivalent to the Jagwire™ guidewire (K922302) manufactured by Microvasive, and the FlexFinder® Guidewire (K964955) manufactured by FlexMedics.

Device Description: Reprocessed guidewires are constructed utilizing a metal alloy that is encapsulated in a striped covering and contains a radiopaque tip. The guidewires are manufactured in a wide range of diameters, lengths, tip angles, and stiffness.

Intended Use: Reprocessed guidewires are intended to be used for selective cannulization of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

K012556
pg 2 of 2

Functional and Safety Testing:

Representative samples of reprocessed guidewires underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

The reprocessed guidewire is substantially equivalent to the Jagwire™ guidewire (K922302) manufactured by Microvasive, and the FlexFinder® Guidewire (K964955) manufactured by FlexMedics.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2002

Mr. Patrick Fleischhacker
V.P. Regulatory and Quality Control
SterilMed, Inc.
11400 73rd Avenue North
MAPLE GROVE MN 55369

Re: K012556
Trade/Device Name: See enclosure
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Regulation Number 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: April 12, 2002
Received: April 16, 2002

Dear Mr. Fleischhacker

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Enclosure 1 K012556 SterilMed Reprocessed Guidewires

Makes and Models of Guidewires

Original Manufacturer: Microvasive
Jagwire

Manufacturer Numbers	Description
5656	.025in, 450cm, Straight
5658	.035in, 450cm, Straight
5659	.035in, 450cm, Angled
5660	.035in, 450cm, Straight, Stiff shaft
5661	.035in, 450cm, Angled, Stiff shaft
5662	.038in, 260cm, Straight
5663	.035in, 260cm, Straight, Stiff shaft
5664	.035in, 260cm, Straight
5665	.035in, 260cm, Angled
5666	.035in, 260cm, Angles, Stiff shaft

K012556
Encl. 2

Indications for use Page

Device Name: Reprocessed Guidewires

Indications for Use:

Reprocessed guidewires are intended to be used for selective cannulization of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012556